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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,749	10/24/2000	CLAUDIA B. JAFFE	01-050210US	2329

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EXAMINER

BROWN, JENNINE M

ART UNIT	PAPER NUMBER
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1755

DATE MAILED: 04/22/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/696,749

Applicant(s)

JAFJE, CLAUDIA B.

Examiner

Jennine M. Brown

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

Examiner has entered Applicants amendment, which obviates Examiners first rejection to claims 1-28, second rejection to claims 2-9 and 19-22, therefore this rejection has been withdrawn.

Examiner withdraws the rejection to the "electroosmotic pump" terminology based on Applicants arguments and further clarification for the record that the electroosmotic pump as defined in the specification is not a separate pump unit or mechanical pumping mechanism installed in the substrate but the pressure created from using electroosmotic movement of fluid in one of the channels which subsequently causes pressure in the adjoining channels and is generally electrode driven.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-9 and 16-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Taylor, et al. (US 6375817).

Taylor et al. teach a microfluidic device having a plurality of channels (Figure 4; col. 4, l. 5-9; col. 8, l. 40-42) a deep channel and a shallow channel with cross sectional areas (col. 2, l. 66-67; col. 5, l. 2-15) having a pressure source in fluid communication with the channel (col. 5, l. 16-50) to introduce one or more samples (col. 4, l. 36-63) and an electrokinetic controller to transport one or more samples through the separation channel by voltage (col. 3, l. 10-15). The channel depth ranges from 0.1 μm to 1000 μm (col. 8, l. 40-47) and the channel widths range from 10 μm to 100 μm (col. 8, l. 40-47). The separation channel has a separation matrix comprising agarose or polyacrylamide gel (col. 5, l. 42-44; col. 7, l. 11-18). The pressure source can be positive pressure (col. 5, l. 18-20) or negative pressure otherwise known as vacuum (col. 6, l. 61-67). One pressure source is an electroosmotic pump. Buffer or salt is used in the channels (col. 3, l. 2-3, 9). Plug injection is used to move the injected sample from the injection channel to the separation channel (col. 2, l. 23-58).

Claims 25-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Nikiforov, et al. (US 6471841).

Nikiforov, et al. teach electroosmotic flow as a means for sample introduction into the separation channel of a microfluidic device with a plurality of channels (col. 1, l. 59-67; col. 7, l. 61 – col. 8, l. 10; col. 13, l. 61 – col. 16, l. 14) where channels have at least one cross sectional dimension of about 0.1 μm to about 500 μm (col. 2, l. 23-37; col. 8, l. 38-57). The applied reference has a common assignee with

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the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor, et al. (US 6375817) as applied to claims 1-9, 16-24 above, and further in view of Christel, et al. (US 6368871).

Taylor, et al. teach a microfluidic device as described previously. Taylor, et al. do not specify the ratio of depth to width. Christel, et al. teach the depth to width ratio is 2:1, 10:1 or more preferably 20:1 (col. 2, l. 49-55; col. 7, l. 44-47; col. 12, l. 60-61).

It would have been obvious to one of ordinary skill in the art to modify the apparatus of Taylor, et al. to use the modified depths because the increased surface area is ideal for mixing of fluids because mixing by diffusion can be very slow and the deeper the channel, the greater surface area which should decrease the length necessary to mix in the channels, making the devices more compact and less expensive to manufacture.

Relevant Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5965410 teaches different widths and depths for channels used in a microfluidic device with electrical control.

US 6174675 teaches a multiport device with novel channel configurations with first and second intersecting channel regions and electrical control.

US 6416642 teaches pressure injection, sample stacking or electrokinetic injection and wicking or pressure to move liquid in a microfluidic system.

Response to Arguments

1. In response to the 112 arguments, Examiner withdraws the rejection to the "electroosmotic pump" terminology based on Applicants arguments and further clarification for the record that the electroosmotic pump as defined in the specification is not a separate pump unit or mechanical pumping mechanism installed in the substrate but the pressure created from using electroosmotic movement of fluid in one of the channels which subsequently causes pressure in the adjoining channels and is generally electrode driven.

2. In response to applicant's argument that the Taylor, et al. (US 6375817) reference fails to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., voltage based electroosmotic pressure pumping) is not recited in the rejected claims (1-9 and 16-26). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants argumentation *admits* that Taylor, et al. teaches pressure introduction into the separation channel (page 5, line 14 – " ... discloses the concept of transporting a sample into the separation channel using pressure.") as well as electrophoretic sample stacking (page 5, line 17 - "... to stack the sample before it is introduced into the separation channel").

As Examiner has previously pointed out, Taylor teaches in column 2, line 25 "A sample plug formation device of the invention generally comprises two intersecting channels, an introduction channel and a separation channel. A sample is introduced through an opening in the first channel, referred herein as a sample introduction channel. The sample moves through the sample introduction channel by vacuum, pressure, capillary action or a combination thereof. At a distance from the point of sample introduction, the sample introduction forms a juncture or junction with (i.e. intersects) a second channel, referred to herein as a separation channel. Through the use of pressure and/or vacuum applied to the separation channel and/or sample introduction channel, a portion of the sample is transported into the separation channel as the bulk sample crosses the junction between the sample introduction and separation channels." Furthermore, on column 3, line 11, "The device may further comprise a voltage generator for applying a voltage axially along the longitudinal axis of the separation channel. The application of a voltage along the separation channel may aid in the separation of components of the sample". Again, column 4, line 8 "...depicted microchip has connections which control the pressure *and/or* voltage through the channels."

Applicants have **not** amended the primary claim to include **electroosmotic pressure introduction** from the introduction channel to the separation channel or mixing channel, rather in amended primary claim 1 ("a pressure source in fluid communication with the mixing channel, which pressure source introduces one or more

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samples into the mixing channel by applying pressure to the mixing channel". Claims 25-27 and 28 are sub claims where the source of pressure is an electroosmotic pump fluidly coupled to the mixing channel.

Therefore previous rejection of claims 1-9 and 16-24 stand as previously stated. Regarding the previous 102(e) rejection of claims 25-28 based on applicants argumentation with regard to Taylor, et al. not specifically teaching electroosmotic pressure for introduction of sample into the separation channel are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new grounds of rejection is made in view of Nikiforov, et al. (US 6471841).

3. Regarding claims 10-15 as rejected under 35 U.S.C. 103(a) being unpatentable over Taylor as applied to claims 1-9 and 16-24 and further in view of Christel, et al. have **not** amended the primary claim to include **electroosmotic pressure introduction** from the introduction channel to the separation channel or mixing channel, rather in amended primary claim 1 ("a pressure source in fluid communication with the mixing channel, which pressure source introduces one or more samples into the mixing channel by applying pressure to the mixing channel". Applicants argumentation *admits* that Taylor, et al. teaches pressure introduction into the separation channel (page 5, line 14 - " ... discloses the concept of transporting a sample into the separation channel using pressure.") as well as electrophoretic sample stacking (page 5, line 17 - "... to stack the sample before it is introduced into the

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separation channel"). Examiner combined Christel with Taylor, et al. because both teach electrophoretic apparatus but Christel, et al. specifically teach different depths and widths for the channel dimensions and specific ratios for these dimensions of the channels because they affect the amount of pressure in each of the chambers depending upon depth. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to combine comes from the modification of the depth and width of the channels to aid in the modification of pressure introduction in the channels for more accurate movement of species from one channel to another. Therefore, the conclusion of obviousness is proper and the rejections stand.

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennine M. Brown whose telephone number is (703) 305-0435. The examiner can normally be reached on M-F 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Bell can be reached on (703) 308-3823. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 879-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

jmb
April 21, 2003


Mark L. Bell
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